

**REMARKS**

**Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

Claims 3-4 have been rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lack of enablement with regard to the recitation of lectins, cofactors, receptors and nucleic acids. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

Claim 1 is drawn to a test kit with at least three affinity reagents, which are specific for different determinants on a protein macromolecule. The Examiner's rejection appears to be based on an erroneous inference made regarding the invention. The Examiner interprets claim 1 as requiring that the affinity reagents bind to protein determinants, i.e. amino acids, because the target macromolecule is a protein. The Examiner then makes the next logical conclusion that the invention is not enabled, in part, because lectins do not bind to amino acids.

However, the inference upon which the rejection is based, i.e. that because the macromolecule is a protein the affinity reagents must bind to amino acids, is incorrect. Many, if not most, proteins are glycosylated. As such, a lectin affinity reagent may bind to the protein macromolecule via the sugar moieties on the protein.

Similarly, the Examiner asserts that nucleic acids do not bind to proteins, but rather to other nucleic acids. However, the

Examiner is incorrect in this regard. There are many known instances of proteins that bind to nucleic acids. For example, protein transcription factors may bind to double-stranded DNA and DNA/RNA aptamers. See, for example, Ellington, A.D. and Szostak, J.W. *Nature* 346:818-822 (1990). Reconsideration of the claims in view of this clarification of the invention is respectfully requested.

**Rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

Claims 2 and 4 have been rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph as being unclear with the assertion that recitation of "specific antigen" in claim 2 renders the claim broader than claim 1, because not all antigens are proteins. The Examiner suggests that claim 2 be amended to recite "protein antigen." Claim 2 has been amended to delete "and the macromolecule is a specific antigen." Withdrawal of the rejection is respectfully requested.

Claims 3 and 4 have been rejected for the recitation of "lectins, receptors, cofactors or nucleic acids" with the assertion that lectins and nucleic acids do not bind to proteins and because the receptors are not defined as protein macromolecule receptors. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

As discussed above, lectins bind to proteins through the sugar moieties that are present on many proteins. In addition, there are many instances of nucleic acid/protein binding. Finally, regarding receptors, Applicants note that the receptors recited in claim 3 are the affinity reagents, not the macromolecule. As such, there is no need to define the receptor to be the target macromolecule, i.e. as a protein macromolecule receptor. Withdrawal of the rejection, is therefore, respectfully requested.


As the above-presented amendments and remarks in no way add new matter or raise new issues for consideration and further address and overcome the rejections of the Examiner, reconsideration and allowance of the claims are respectfully requested. Should the Examiner have any questions regarding the present application, she is requested to contact MaryAnne Armstrong, PhD (Reg. No. 40,069) in the Washington DC area, at (703) 205-8000.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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